

REMARKS

I. **INTRODUCTION**

Claims 51-72 are currently pending in the present application. In view of the following remarks, Applicant respectfully submits that the pending claims are now in condition for allowance.

II. **REJECTIONS UNDER 35 U.S.C. § 102(b)**

Claims 51-64 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Doyle *et al.* (Advances in Critical Care Testing, Eds. Muller and McQueen, Springer-Verlag Telos, January 1997; reference A17 on the PTOL-1449 of 10/18/00). This rejection has been maintained from the previous Office Action, and thus Applicant hereby incorporates by reference all previous arguments made in the previous response mailed on October 31, 2007. Furthermore, for at least the following reasons, Applicant respectfully submits that Doyle *et al.* does not disclose or suggest the claimed patient populations, and thus does not anticipate the pending claims.

The method of the present invention, as currently recited in independent claim 51, is directed to a mammal that is “asymptomatic to lung damage or wherein the clinical diagnosis of lung damage in said mammal cannot otherwise be confirmed without the aid of one or more invasive procedures.” Claims 52-56 and 63 ultimately depend from claim 51 and thus include this limitation as well. Similarly, the method of the present invention, as currently recited in independent claim 57, is directed to a mammal that is “asymptomatic to alveolo-capillary membrane damage or wherein the clinical diagnosis of alveolo-capillary membrane damage in said mammal cannot otherwise be confirmed without the aid of one or

more invasive procedures.” Claims 58-62 and 64 ultimately depend from claim 57 and thus include this limitation as well. That is, the methods of the pending claims do not cover just any mammal, but only those specifically recited mammals as articulated in the claims. In this regard, Applicant notes that the discussion on page 3 of the Office Action mailed on July 3, 2008 concerning the claim limitation of being “predisposed to developing lung damage” is not relevant to the pending claims which do not include this limitation.

To anticipate a claim, a reference must disclose each and every element of the claimed invention. *Verdergaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 2 USPQ2d 1051 (Fed. Cir. 1987). Furthermore, “[t]o establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.’” *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted) (emphasis added); *see also In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993) (CAFC reversed obviousness rejection because inherency was based on “optimal” conditions, and the means for achieving such “optimal” conditions were not explicitly or implicitly disclosed in prior art); M.P.E.P. § 2112, IV. Thus, the M.P.E.P. and the case law make clear that simply because a certain result or characteristic *may* occur in the prior art does not establish the inherency of that result or characteristic.

The Office Action mailed on July 3, 2008 has misstated the prior arguments made by the Applicant. On page 5 of the Office Action, it states that “Applicants argue that no evidence of cardiorespiratory disease is not equivalent to no evidence of lung damage or asymptomatic and that *the patient populations are necessarily different*” (emphasis added).

In fact, Applicant has argued that Doyle *et al.* does not disclose that a member of the normal group or OD group are necessarily “asymptomatic to” lung damage or alveolo-capillary membrane damage, or necessarily of a condition that the clinical diagnosis of lung damage or alveolo-capillary membrane damage in the mammal “cannot otherwise be confirmed without the aid of one or more invasive procedures.” That is, Applicant has argued that the patient populations are not necessarily the same. This is the legal standard for inherent anticipation, and Applicant respectfully submits that this standard has not been met by Doyle *et al.* in regard to the pending claims.

The Office Action mailed on July 3, 2008 argues that “[i]n order to be classified “normal” with respect to lung injury or alveolar-capillary membrane damage the skilled artisan would have taken into account the disease basis for comparison. As such, the degree of analysis of the population would be the same.” (Office Action mailed on July 3, 2008; pages 3-4). Applicant respectfully disagrees with this assertion, as the “normal” group in Doyle *et al.* is not disclosed as being “normal” with respect to lung injury or alveolar-capillary membrane damage. In fact, it is not clear from Doyle *et al.* to what extent the “normal” individuals were screened prior to their placement in the “normal” group. As such, the degree of analysis of the “normal” individuals in Doyle *et al.* can not be determined with certainty, and thus they can not necessarily be equated with individuals who are “asymptomatic to” lung damage or alveolo-capillary membrane damage, or of a condition that the clinical diagnosis of lung damage or alveolo-capillary membrane damage in the individual “cannot otherwise be confirmed without the aid of one or more invasive procedures.”

The Office Action mailed on July 3, 2008 also argues that “[a] person who is used for a basis for comparison in a disease analysis of different patient populations has to have been assessed for the lung/alveolar capillary membrane damage, otherwise the person could not have been classified as “normal.” This is the scientific method standard.” (Office Action mailed on July 3, 2008; page 4). However, Applicant has previously submitted and discussed an article by Martine Remy-Jardin *et al.*, *Morphologic Effects of Cigarette Smoking on Airways and Pulmonary Parenchyma in Healthy Adult Volunteers: CT Evaluation and Correlation with Pulmonary Function Tests*, Radiology, Volume 186(1):107-115 (1993) (“Remy-Jardin *et al.*”), which illustrates how an individual could be within the normal or OD groups of Doyle *et al.*, yet still not be within the scope of the patient populations of the pending claims (*i.e.*, a healthy smoker with no evidence of cardiorespiratory disease, who was not asymptomatic to lung damage and who had lung damage (emphysema) which could be confirmed without the aid of an invasive procedure). Thus, Remy-Jardin *et al.* provides a documented, contemporary study which demonstrates that a healthy individual in the context of a pulmonary study need not be asymptomatic to lung damage. In this regard, we agree with the statement in the Office Action that “[o]ne skilled in the art simply does not use people having the disease as “normals” in scientific study.” (Office Action mailed on July 3, 2008; page 4). However, the issue is not whether the individuals in the normal or OD groups of Doyle *et al.* were diagnosed with APE or ARDS – which we agree, they were not. The issue is whether the individuals in the normal or OD groups of Doyle *et al.* were necessarily “asymptomatic to” lung damage or alveolo-capillary membrane damage, or necessarily of a condition that the clinical diagnosis of lung damage or alveolo-capillary membrane damage in the individual “cannot otherwise be confirmed without the aid of one or more invasive procedures,” and Applicant respectfully submits that they were not.

In sum, Doyle *et al.* does not disclose or suggest that a member of the normal group or OD group are necessarily “asymptomatic to” lung damage or alveolo-capillary membrane damage, or necessarily of a condition that the clinical diagnosis of lung damage or alveolo-capillary membrane damage in the individual “cannot otherwise be confirmed without the aid of one or more invasive procedures.” Doyle *et al.* therefore does not inherently anticipate the presently claimed invention. Thus, for at least the preceding reasons, it is respectfully submitted that the rejections under 35 U.S.C. § 102(b) have been overcome and should therefore be withdrawn.

III. REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 51-72 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Doyle *et al.* (Am. J. Respir. Crit. Care Med. 1994; 149; A576) (“Doyle A”) in view of Doyle *et al.* (Advances in Critical Care Testing, Eds. Muller and McQueen, Springer-Verlag Telos, January 1997; reference A17 on the PTOL-1449 of 10/18/00) (“Doyle B”), Doyle *et al.* (Am. J. Respir. Crit. Care Med. 152:307-317, 1995) (“Doyle C”), Honda (Japanese Journal of Thoracic Diseases, 34 Suppl Abstract only, December 1996; reference A11 on PTOL-1449 of 6/6/00) and Abe *et al.* (Japanese Journal of Thoracic Diseases, 33(11):1219, Abstract only, November 1995; reference A10 on PTOL-1449 of 6/6/00). Applicant respectfully submits that these rejections should be withdrawn for at least the following reasons.

As described above in regard to the anticipation rejections, Doyle B does not disclose or suggest the claim recitation of “wherein the mammal is asymptomatic to lung damage or wherein the clinical diagnosis of lung damage in the mammal cannot otherwise be confirmed without the aid of one or more invasive procedures,” as currently recited in claims

51-56, 63 and 65-68. Likewise, Doyle B does not disclose or suggest the claim recitation of “wherein the mammal is asymptomatic to alveolo-capillary membrane damage or wherein the clinical diagnosis of alveolo-capillary membrane damage in the mammal cannot otherwise be confirmed without the aid of one or more invasive procedures,” as currently recited in claims 57-62, 64 and 69-72.

Neither Doyle A, Doyle C, Honda nor Abe *et al.* cure the shortcomings of Doyle B. That is, neither Doyle A, Doyle C, Honda nor Abe *et al.* disclose or suggest that the individuals therein are necessarily “asymptomatic to” lung damage or alveolo-capillary membrane damage, or that the clinical diagnosis of lung damage or alveolo-capillary membrane damage in the mammal “cannot otherwise be confirmed without the aid of one or more invasive procedures.”

Thus, for at least the preceding reasons it is respectfully submitted that the rejections under 35 U.S.C. § 103(a) should be withdrawn.

IV. CONCLUSION

In light of the foregoing, Applicant respectfully submits that all pending claims are in condition for allowance. Prompt reconsideration and allowance of the present application are therefore earnestly solicited.

Respectfully submitted,
KENYON & KENYON LLP

Dated: January 5, 2009

By:



Kevin T. Godlewski
(Reg. No. 47,598)

KENYON & KENYON LLP
One Broadway
New York, NY 10004
Telephone: (212) 425-7200
Facsimile: (212) 425-5288
CUSTOMER NO.: 26646